Litigation Advisory

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Supreme Court Finds Impossibility Preemption for Failure-To-Warn Claims Against Generic Drug Manufacturers

On June 23 the Supreme Court added another split decision to its long line of seemingly irreconcilable opinions on federal preemption of state-law product liability claims involving federally regulated products. In a 5-4 decision authored by Justice Thomas, the Court held in ***Pliva v. Mensing*, No. 09-993**, that state failure-to-warn claims involving generic drugs are preempted by the federal Food, Drug and Cosmetic Act ("FDCA"). The Court majority held that it is impossible for a generic drug manufacturer to comply both with a state tort duty requiring additional warnings on product labeling and federal requirements that prohibit generic drug manufacturers from using warnings that differ in any substantive way from the from the brand-name drug manufacturer's federally-approved labeling.

In 2009, the Court held in *Wyeth v. Levine*, 129 S. Ct. 1187 (2009), that the FDCA does *not* preempt failure-to-warn claims involving brand-name drugs. In that case, a divided Court found that brand name manufacturers have the flexibility to add or strengthen warnings independently, and that state-law failure-to-warn claims would be preempted only if the Food and Drug Administration (FDA) had considered and rejected the allegedly omitted warning. The majority opinion in *Mensing* acknowledges that from the plaintiffs' viewpoint, "finding pre-emption here but not in *Wyeth* makes little sense," but explains that "different federal statutes may, as here, lead to different pre-emption results." Slip op. at 18-19.

In his opinion, Justice Thomas discusses FDA's generic drug manufacturer regulations, which require warnings that are the "same as" warnings approved by the FDA for the equivalent brand-name drug. He concludes that it would be impossible for a generic manufacturer to comply with both its federal obligations to duplicate the brand-name manufacturer's labeling and any state tort duty to provide stronger warnings. Slip op. at 6. In doing so, the Court rejected the plaintiffs' contentions that generic manufacturers have options to strengthen product warnings, even in the absence of FDA direction. Rather, the Court deferred to FDA's interpretation that generic manufacturers cannot make unilateral labeling and warning changes. *Id*. at 8, 9.

The majority assumed, but did not decide, that generic manufacturers may have a duty under federal law to propose stronger warning labels to the FDA, but found that any such a duty was not a matter of state concern. Slip op. at 12. Rather, the Court found that "when a party cannot satisfy its state duties without the Federal Government's special permission and assistance, which is dependent on the exercise of judgment by a federal agency, that party cannot independently satisfy those state duties for preemption purposes." Slip op. at 17.

The majority acknowledges that its opinion potentially deprives plaintiffs of a state law tort remedy based on the seemingly random decision of a physician or pharmacist to prescribe or dispense a generic rather than a brand-name drug. The Court points out, however that Congress made a decision to impose different duties on different manufacturers, thus raising the possibility of different preemption results: "[I]t is not this Court's task to decide whether the statutory scheme established by Congress is unusual or even bizarre." *Id*. at 19. The Court further notes that Congress is empowered to change the laws regulating generic and brand name drugs at any time.

In a 21-page dissent, Justice Sotomayor, joined by Justices Ginsburg, Breyer and Kagan, argues that the Court has diminished the "demanding" standard for impossibility preemption, and that it "makes little sense" for a plaintiff's legal remedies to turn on whether a prescription was filled with a brand name or a generic. Slip op. at 2 (Sotomayor, J., dissenting). According to the dissent, claims should not be preempted on a supposition that a manufacturer *might* have been unable to comply with state law, but only when the manufacturer can show that FDA rejected the allegedly-omitted warning. Justice Sotomayor asserted that "this conclusion flows naturally from the overarching principles of state sovereignty in health related issues and the presumption against pre-emption that govern the pre-emption doctrine." *Id*. at 13. "Any other approach threatens to infringe the States' authority over traditional matters of state interest—such as the failure-to-warn claims here—when Congress expressed no intent to pre-empt state law." *Id*.

This case is a big win for the generic drug industry, and could end a large number of product liability claims against those companies. In larger sense, the case adds another perplexing layer to the jurisprudence of preemption in product liability claims. While it remains difficult or impossible to harmonize the Supreme Court's varying opinions on preemption of federally-regulated products, it is clear that the availability of a federal preemption defense is very dependent on the specific regulatory scheme.